User's Manual

Forza

⚠ **Read this manual carefully before using Forza.**

CE 0476 This product is manufactured in compliance with the CE European Medical Device Directive and later directives and additions (2007/47 directive) and according to the reference norms **CEI EN 60601-1, 60601-1-2, 60601-1-11, 60601-2- 40, 60601-1-6, CEI IEC 62304, Directive 2002/96/CEE**

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SYMBOLS USED

The graphic symbols used on this device and on this manual refer to the UNI EN ISO 980 Law, CEI EN 60601-1, RAEE Law and 2002/96/ECC Directive.

SYMBOL	DESCRIPTION
	Serial Number
	Class II device
	Warning, read the instructions before using the device. This symbol could also be used as a “Warning” symbol
	Read the instructions of use
	Manufacturer
	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary following the 2002/96/EC Law of the European Parliament and Council of the European Union about the disposal of e-waste.

The Forza device has been tested in reference to the EN 60601-1 and the EN 60601-1-2 Law. If the user connects the Forza device to any other unauthorized device following the EN 606011 and EN 60601-1-2 Laws, he/she has to ensure that the combined use of the two devices follows the laws above mentioned.

Otherwise OT Bioelettronica shall not be held liable for accidents and/or injuries to persons or damage. For the features of the software, please read the Software Manual.

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1. GENERAL DESCRIPTION

The Forza is single channel general purpose amplifier. This system has been designed to amplify and to filter any differential single ended signals.

The information detected from the input are conditioned and then transferred to a PC with a wired connection (USB) or with a wireless connection (Bluetooth), or available in analog modality on the output connector.

Forza connected to a PC via USB:

Forza works with a software named OT BioLab in order to display and process the data. This software is part of the Forza system and it is also possible to download it for free on the website www.otbioelettronica.it in the Downloads section.

Forza connected to a Tablet or Smartphone via Bluetooth:

Forza works with an App called Forza (downloadable on the playstore), with this App is possible to display acquired data.

Forza in analog mode:

Forza can be connected to other devices (eg. To the AUX-IN connector of the devices: EMG-USB2+, EMG-USB e MEBA) or it can be connected to a standard acquisition board or to an oscilloscope.

2. INTENDED USE

Forza has been designed to be used as a force measurement device for signal produced by load cells or torque-meters with differential output.

⚠ **The device is not intended to be used near inflammable anaesthetics.**

3. PLACE OF USE

Forza is intended to be used primarily as a laboratory device and secondly as a hospital device: as a home device, the patient uses the device at home during the day and as a hospital device the operator uses the information detected from it in order to make a diagnosis.

4. USER PROFILE

USER: Specialized operator

a) Knowledge: Minimum. Basic notions about physics
b) Languages: Italian and/or English
c) Experience: Minimum. Minimum training about the device use
d) Handicaps:
    - Maximum reduction of the hearing of 40% with residual hearing at 60%;
    - Maximum sight reduction of 40% with residual sight at 60%

5. SAFETY CAUTIONS AND WARNINGS

The use of Forza is forbidden in the following conditions:

- Simultaneous use of electro surgery systems, shortwave or microwave therapy or near these type of devices;
- Unsound mind patient;
- The device is damaged;
- Near inflammable anaesthetics with air, oxygen or nitrous oxide.
- To make an electrocardiographic exam

These warnings must be followed:

- Contact immediately the manufacturer if foreign materials (liquids, etc.) come into contact with the device.
- If the device falls in to the ground or something similar happens, check if the device is undamaged. In case of doubt, contact the manufacturer.

The Forza could be sensitive to electromagnetic interferences of other devices that could alter its electromyography measurements and consequently the variables calculated on the basis of the information detected. For this reason, do not use it near devices that could cause the problems described above, for example mobile phones, instruments with power transformer, etc.

- The operator must be sure that the battery of the device is completely charged following what is indicated in this User's Manual before to use the device.
- The device must be kept out of reach of children or unsound mind patient

- Do not clean the device using acetone, ether, freon, oil products or any other solvent
- Do not use soap or water on the connector pin
- Do not clean Forza or connection cables with water, in autoclave or steam cleaning

⚠ The device must not be used in any other way than indicated in these instructions

6. CONTENT OF THE FORZA KIT

ACCESSORIES AND DOCUMENTS			
REF	**Description**	**Features**	
CUSB03	USB connection cable to recharge internal battery and for PC connection.	**UNSTERILE**	**REUSABLE**
J-BNCcable	2,5mm 4 poles Jack . BNC cable	**UNSTERILE**	**REUSABLE**

⚠ The accessories of the machine indicated above are to be considered as part of the device itself, so they are not subject to CE marking.

ACCESSORIES NEEDED BUT NOT INCLUDED IN THE STANDARD EQUIPMENT			
REF	**Description**	**STERILE**	**SINGLE-USE**
LOADKg	Load cell with 4 pin output connector and bridge configuration	**NO**	**YES**

⚠ **Use of the equipment accessories and/or** CE accessories of the OT Bioelettronica to be used for the detection of the force signals.

7. DETAILED DESCRIPTION

Controls, indicators and connectors of the Forza are shown in Fig. 1 and described in the following section.

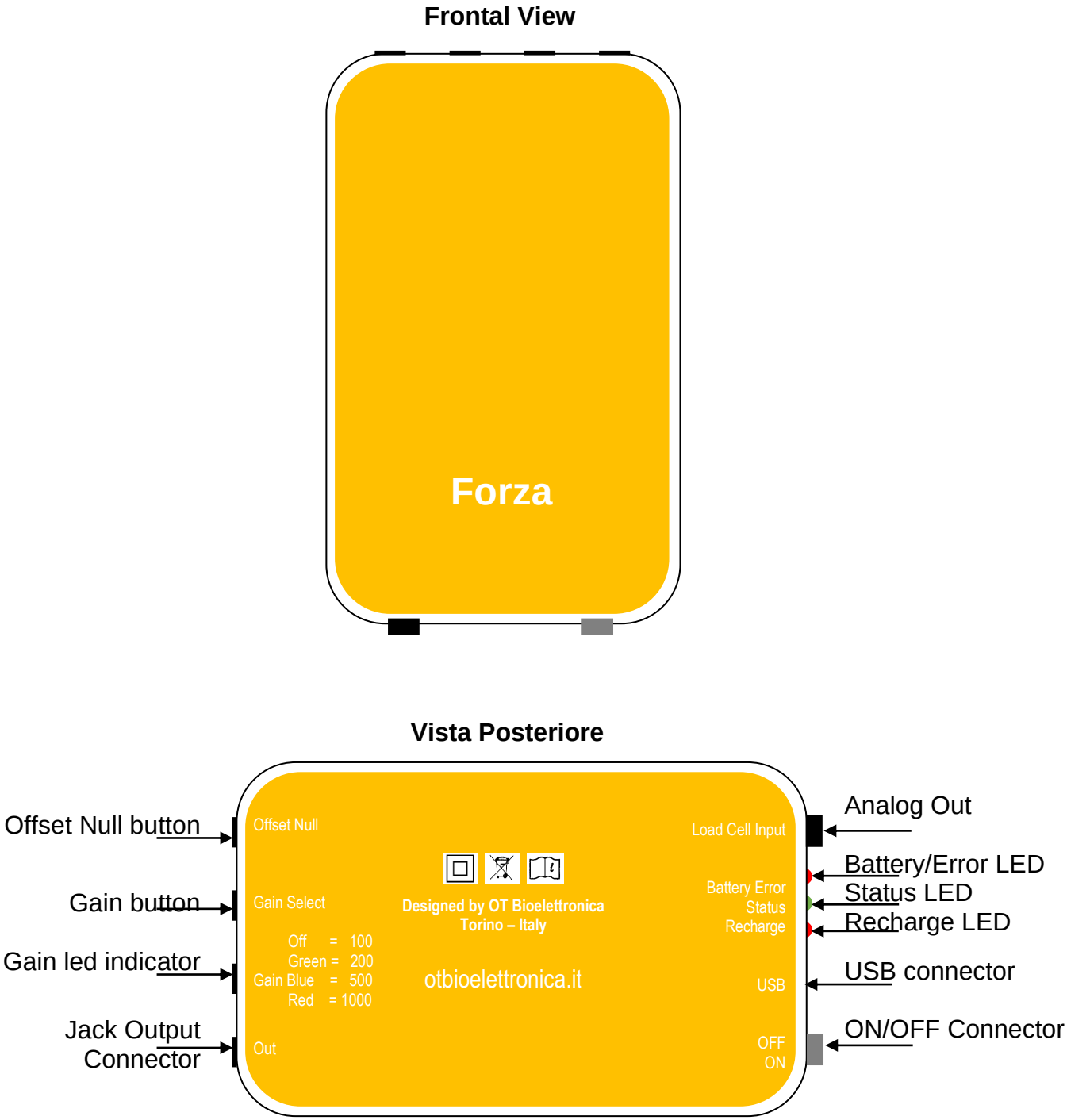


Fig. 1: *Front view and Back view of the Forza*

7.1 Controls and indicators

Description of controls, indicators and connectors shown in fig.1:

- Load Cell Input: This input allow the connection of bridge tranducers like load cells.

- Battery/Error LED: This red LED is normally off, it switch on when the battery is empty and when there is some loose of data during Bluetooth transmission.

- Status LED: This LED flashes blue when Forza is working.

- Recharge LED: This red LED switches on to indicate that battery are under charge. It switch off when battery are fully recharged.

- USB connector: this connector is used to recharge battery and to transfer data from Forza to the PC.

- **ON/OFF switch:** With this switch is possible to turn off and on the Forza system.

When the system is connected via USB to the PC it is automatically on, independently of the ON/OFF switch position.

- **Offset Null** button: this button allows you to reset the output offset of Forza in the analog mode use (for digital mode use offset reset occurs via SW or via App) .

- **Gain Select** button: this button allows you to change the system gains in the analog mode use (digital mode use has fixed gain of 100V/V) .

- **Gain** led: this led shows the selected gain with different colors: gain 100 = led off, gain 200 = light green, gain 500 = light blue , gain 1000 = red LED)

- **OUT**: At this connector is available the analog force signal amplified, filtered and with the possibility to delete offset (everything is after the optical isolation of the device).

7.2 Adapters

Forza adapters: the analog output signal of Forza available on the output OUT can be sent to other systems with the J - BNC adapter cable that allows to connect Forza to other devices with BNC input (other custom adapters can be developed to connect Forza device to other devices that have inputs different from the classic BNC).

USB cable: charge battery cable

The Forza device has as accessory a USB cable called CUSB03 (USB – miniUSB). This cable allows charging Forza by its connection to a USB PC port or to a power supplier that incorporates an USB output.

7.3 System requirements for PC and Tablet connection

System Requirements for PC connection of Forza

1. Windows Operating system for PC (Windows XP, Vista, Windows 7, Windows 8)
2. USB port to recharge the Forza equipment

System Requirements for Tablet connection of Forza

1. Android version starting from the 4.0
2. Bluetooth starting from the 2.0

7.4 Battery charge process

Behaviour of the device during battery charge process

During the battery charge process the red Recharge LED, located on the Forza right side (posterior view) becomes red till the end of the recharge process, when the battery is fully charged the red LED switches off.

⚠ **Charge the device for at least 2 hours before to use it.**

7.5 Use of Forza

Application and acquisition with the Forza device

To use the Forza system properly, please follow these instructions:

PC use of Forza:

• connect the load cell to the Forza device using the Load Cell Input ;

• connect the device to your PC using CUSB03 cable;

• launch the SW OT BioLab and select the device Forza;

• create the appropriate setup and enter the values of sensitivity and full scale of the load cell;

• delete offset via SW and proceed with the display of the signal

Tablet and Smartphone use of Forza:

• connect the load cell to the Forza device using the Load Cell Input;

• pair the device Forza to a Tablet or to a Smartphone via Bluetooth;

• launch the application called Forza;

• press connect button from the application ;

• set the values of sensitivity and full scale use of the load cell in the App ;

• delete offset from the App and proceed with the acquisition of the signal

Analog mode use of Forza:

• connect the load cell to the Forza device using the Load Cell Input;

• connect the device to an acquisition system using the cable called J-BNCcable;

• adjust the gain of the system using the button Gain Select;

• delete the offset using the button Offset Null

Formula for the force calculation:

$$\text{Force (Kg)} = [V_{\text{out measured}}(V) * \text{F.S.(Kg)}] \; / \; [\text{Sensibility (mV/V)} * 5\ (V) * \text{Gain (V/V)}]$$

8. TROUBLESHOOTING

This section describes the most common problems that may be found by Forza users.

Problem Description	How to deal with it
After the Forza switch-on the Bluetooth connection is not available	Check the Battery charge
The red LED Error is switched-on	Battery empty, so recharge it or Data transmission error, please move near to the PC, tablet, smartphone with Forza device

9. FORZA MAINTENANCE AND STORAGE

Forza has to be used, transported and stored in the following conditions:

Temperature:	**from 10°C to +40°C**
Maximum relative humidity:	**from 30% to 75%**
Atmospheric pressure:	**from 700 hPa to 1060 hPa**

It is recommended to turn off the Forza at the end of every session.
The Forza should be stored with all the enclosed accessories on a safe place far from all conditions described in the Warnings section of this manual. The Forza does not need any particular maintenance procedure to work. To maintain the battery efficiency, recharge the device before every use and check regularly the efficiency status of the battery.

⚠ If during the use and after the battery charging the battery lasts less than 1 hour, contact the manufacturer to check the electrical source itself.

Cleaning the device: At the end of every use, please clean the Forza with a clean cloth.

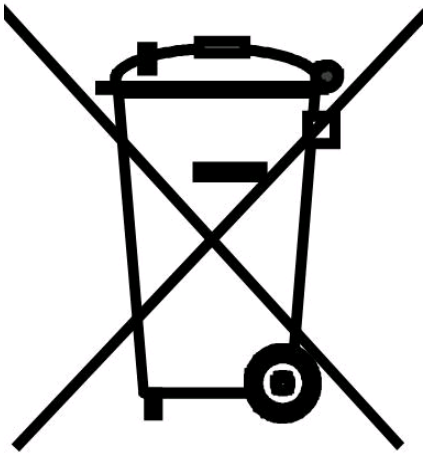
- ⚠ Do not clean the Forza using acetone, ether, freon, oil products or any other solvent;

  ⚠ Do not use soap or water on the connectors pin contacts.
- ⚠ Do not clean the Forza or its cables with water, in autoclave or with steam cleaning**.**

⚠ **WARNING: clean electrodes adapter cable only with hospital disinfectants before every use to avoid microbial contamination between patients and healthcare professionals.**

Product Disposal

The Forza contains electronic parts that must be disposed of as e-waste. Dispose the device and the accessories following local regulations. Follow the disposal regulations of your country in order to ensure the correct disposal of the Forza and its accessories. For further information about the disposal of this device, contact the Environment Department and local authority.



⚠ **Warning**: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment of necessary, following the 2002/96/EC of the European Parliament and European Council on waste electrical and electronic equipment.
(WEEE). The regulation is not valid in case of corrupted product.

Life span of the device

The Forza system is produced in order to last if the use and maintenance conditions indicated in this User's manual are followed. The life span of the device is determined by the life span of the battery (5 years). After this period it is recommended to take the device to the manufacturer every two years.

10. TECHNICAL SPECIFICATIONS

The Forza device is a battery system designed following the medical regulations in order to ensure the patient safety.

The signal amplified by the system is transferred to a PC by wired USB cable or to a Tablet by wireless (Bluetooth) modalities.

In table 1 technical specifications of the Forza device are reported.

Model	Forza
Classification	Battery system
Degree of Protection	IP32
Case	Plastic case
Power Supply	3,7V Battery, rechargeable
Battery time	8 Hours (full charge)
Charging time	2 hours
Class	II
Numbers of Channels	1
Dynamic	0 ÷ 50 mV_{PP}
Bandwidth	0 ÷ 33Hz
Input Noise	< 10 μV_{RMS}
Gain (digital mode)	100 V/V
Gain (analog mode)	Selectable: 100-200-500-1000 V/V
CMRR	>96 dB
Output Dynamics	0 ÷ 5 V
A/D converter resolution	24 bits
Wireless transmission modality	Bluetooth
Wired transmission modality	USB
Sampling rate	100 Hz
Dimensions	59 x 95 x 20 mm
Weight	100g

TAB. 1: *Technical Specifications of the Forza device*

11. CUSTOMER SERVICE and WARRANTY

CUSTOMER SERVICE

Forza has no parts that can be replaced or repaired by the user; contact the distributor for assistance so that he/she can repair or replace the products under warranty.

Maintenance and replacement of parts, modifications and/or reparations made by unauthorized Companies and/or operators by OT Bioelettronica will forfeit entitlement to warranty.
OT Bioelettronica denies any and all responsibility for damages caused directly or indirectly as a result of maintenance, replacement of parts, modifications and/or reparations made by Companies and/or operator that are not authorized by the OT Bioelettronica
Forza does not need any prior maintenance.

WARRANTY

OT Bioelettronica ensures that every new product has no defects due to materials and labour and will repair and/or replace in warranty products used following the intended use and used in the use conditions described in this manual.

Warranty lasts **2 years** only after filling and signature of the warranty application form that you find below.

Warranty conditions: the obligations of OT Bioelettronica following the warranty are limited exclusively to what follows:
- reparation will be made by and no later than 30 work days after the receipt of the product and only after the verification that the malfunctioning is not due to inadequate or inaccurate use, maintenance and /or reparation.

If OT Bioelettronica verifies that the malfunctioning is not due to inadequate or inaccurate use or unauthorized maintenance/reparation, the reparation costs (materials and labour) will be invoiced only after acceptation of the budget of reparation by the owner.

These warranty conditions substitute all the other warranty conditions, explicit or implicit, included, but not within limits of the general conditions specified in the international sale regulations.

OT Bioelettronica reserves the right to refuse the reparation of any products sent by the user for reparation; this refusal will be conveniently explained. The only obligation of OT Bioelettronica is that of returning the product to the user at its own expenses.

Manufactured by:

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